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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/852,495	05/07/97	RUDDY D	17957-000110

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EXAMINER	
VANDERVEGT,F	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 03/27/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/852,495	Applicant(s) Ruddy et al
	Examiner F. Pierre VanderVegt	Group Art Unit 1816

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ~~1 month(s), or~~ thirty days, ~~whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-28* ~~is~~/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-28* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply with the Sequence Rules and marked-up Raw Sequence Listing

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a continuation-in-part of application S.N. 08/724,394, which is a continuation-in-part of application S.N. 08/630,912, which is a continuation-in-part of application S.N. 08/652,265.

Claims 1-28 are currently pending in this application.

1. This application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must provide a substitute CRF, substitute paper copy and a new statement that the content of the CRF and the paper copy are the same and that they contain no new matter. See MPEP 2422.03-2422.04.

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the CRF which is part of this application. A copy of the of the printout detailing the errors is included with this communication to assist Applicant in correcting the errors.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 26, drawn to 8-100 bp oligonucleotides from the human hemochromatosis gene region containing a polymorphism and a kit comprising same, classified in class 536, subclass 23.1 and class 435, subclass 810, respectively.

II. Claims 4 and 27, drawn to oligonucleotide pairs from the human hemochromatosis gene region and a kit comprising same, classified in class 536, subclass 23.1 and class 435, subclass 810, respectively.

III. Claims 5-11, drawn to nucleic acid fragments of 100 bp to 235 kb from the human hemochromatosis gene region containing a polymorphism, classified in class 536, subclass 23.5.

IV. Claim 12, drawn to a polypeptide from the human hemochromatosis gene region containing a polymorphism, classified in class 530, subclass 350.

V. Claim 13, drawn to an antibody to a polypeptide from the human hemochromatosis gene region containing a polymorphism, classified in class 530, subclass 387.1.

VI. Claims 14-25, drawn to a nucleic acid based assay for a human hemochromatosis gene region containing a polymorphism, classified in class 435, subclass 4.

VII. Claim 28, drawn to a specifically identified lymphoblastoid cell line, classified in class 435, subclass 372.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the oligonucleotide of Group I contain within their sequence a polymorphism found within the human hemochromatosis gene region while the oligonucleotide pairs of Group II are sequences which may not contain polymorphisms themselves, but the members of the pair are derived from sequences within the human hemochromatosis gene region found on either side of a polymorphism for the purpose of amplifying the sequence containing the polymorphism.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the oligonucleotides of Group I are small segments of DNA which are derived from the immediate vicinity of, and containing, a polymorphism, while the nucleic acid sequences of Group III are larger segments which not only contain polymorphisms, but may encode entire or multiple gene products.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In

the instant case the different inventions are drawn to nucleic acid sequences, composed of nucleotides, and polypeptides, composed of amino acids. The compounds are made of different basic building blocks and exhibit different physicochemical properties. Further, the polypeptides of Group IV can be obtained without isolation of the nucleic acids of Group III by purification from their natural source.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they antibody of Group V can be directed to a region of the protein which does not contain a polymorphism and therefore would also recognize the normal, non-polymorphic protein and can be used to isolate same.

Inventions I, II and VI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid-based assay of group VI is not strictly dependent upon the oligonucleotide pairs of Group II or by measuring annealing of an oligonucleotide sequence containing a particular mutation of Group I, but can be performed by any method available to the skilled artisan for probing for specific nucleic acid sequences.

Inventions I, III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the oligonucleotides of Groups I and III encompass mutations to the human hemochromatosis gene region not present in the cell line of Group VII.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In

the instant case the different inventions are unrelated because the antibody of Group V is not used in the nucleic acid-based assay of Group VI.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. A telephone call was made to Victor Lee on March 16, 1998 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Conclusion

7. As stated orally to Mr. Lee, the Examiner respectfully requests that, whichever Group is elected, the claims be amended in a manner which will place the claims into better condition for examination. Such an amendment would greatly assist in expediting prosecution of the application.

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

9. Effective February 7, 1998, the Group and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1644.

10. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014. *Communications which are not to be entered into the record, such as proposed amendments, should be clearly marked "DRAFT" and faxed to (703)305-7401.*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Monday through Friday from 8:00 am to 4:30 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

March 24, 1998
F. Pierre VanderVegt, Ph.D.
Patent Examiner
Art Unit 1644

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644